beurer medical

instructions for use

mg/dL

GL44

GB

Codefree

BLOOD GLUCOSE MONITOR

Step by step

EINFACHE BEDIENUNG
easy to use

germanengineering

IVD

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CE 0483

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1 Getting to know your instrument

Dear Customer,

Thank you for choosing one of our products. Our name stands for high-quality, thoroughly tested products for applications in the areas of heat, weight, blood pressure, blood glucose measurement, body temperature, pulse, gentle therapy, massage and air.
Please read these Instructions for Use carefully and keep them for later use, be sure to make them accessible to other users and observe the notes they contain.

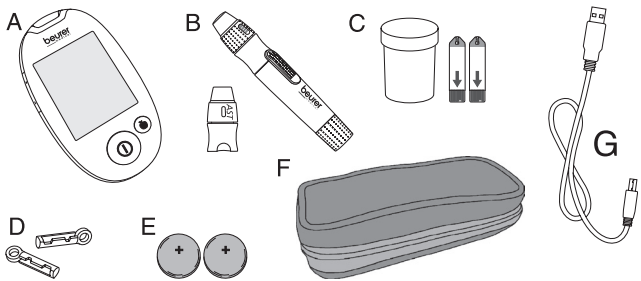
With kind regards
Your Beurer team.

Getting to know your instrument

The GL44 blood glucose monitor is intended for fast and simple blood glucose measurement of fresh capillary blood samples, either for self-testing or in a clinical environment by trained personnel. It enables quick and easy blood glucose measurement, measured values to be stored and the average of all measured values to be displayed to ideally assist you in monitoring diabetes. The test is performed exclusively externally (IVD).
The large backlit display shows measured values clearly. The user-friendly design with handy test strips and a reduction in the controls to a few buttons guarantee simple, yet reliable measurements. The device can be connected directly to a PC using the USB cable provided. You can evaluate the measured values on your PC using blood glucose diary software and use the results to monitor your blood glucose values.
Beurer blood glucose software is available as a free download at www.beurer.com

1.1 Delivery scope, replacements and accessories

Check that the set packaging has not been tampered with and check the contents for completeness. Before use, ensure that all packaging materials are removed and that there is no visible damage to the unit or accessories. When in doubt, do not use the unit and contact your dealer or the customer service address provided.



A	1 Blood glucose monitor
B	1 Lancing device with AST cap to take blood samples from alternative body parts
C	10 test strips
D	10 sterile lancet needles
E	2 button cell batteries, 3 V CR2032 (already inserted)
F	1 practical case
G	1 USB cable
	These Instructions for use, additional information

- If the packaging has sustained considerable damage or the contents are incomplete, please return the system to your retailer.
- The blood glucose monitor, test strips and additionally available control solutions have been specially designed to complement each other. For this reason, use only test strips and control solutions that have been approved for this blood glucose monitor.

Note

- Use original manufacturer accessories only.

Follow-up purchases

You can also obtain test strips, control solution and lancet needles without a prescription.

Item	REF
50 test strips	REF 464.15
100 test strips	REF 464.13
Control solution LEVEL 3 and 4	REF 464.16
100 lancet needles	REF 457.01

1.2 Functions of the device

This device is intended for measuring the blood glucose content in human blood. It is also suitable for self-testing at home.

The blood glucose monitor enables you to quickly and simply:

- Measure your blood glucose level,
- Display, highlight and save measured values,
- Display the average measured blood glucose value from the last 7, 14, 30 and 90 days,
- Display the average of the highlighted measured blood glucose values from the last 7, 14, 30 and 90 days,
- Set the time and date,
- Transfer stored measured values to a PC for evaluation (additional accessories required).

The blood glucose monitor also includes the following monitoring functions:

- Warning in the event of unsuitable temperatures.
- Low battery display.
- Low test strips warning.

Warning

- **Do not use the device to diagnose diabetes; it is intended for regular monitoring only.**
- **Please consult your GP with regard to insulin doses.**

1.3 Signs and symbols

The symbols on the packaging, type plate of the blood glucose monitor and accessories represent the following:

IVD	In vitro diagnostics
SN	Serial number
2°C 30°C	Temperature limit +2 °C to +30 °C
2	Not for re-use/For single use only
	Use by
3 M	Maximum shelf life after initial opening in months
LOT	Batch designation
STERILE R	Sterilised by radiation (lancets)
	Warning, please observe accompanying documents

	Manufacturer
	Please observe the Instructions for Use
PCT	PCT: certification symbol for products that are exported to the Russian Federation and members of the CIS
	Green dot (Der Grüne Punkt): German dual waste collection system
Σ <n>	Contents sufficient for <n> tests
REF / Art.-Nr.	Order number
mg/dL	Unit of measurement for blood glucose value
	Biohazard, risk of infection

In the Instructions for Use, the symbols represent the following:

Warning

Warning indicating a risk of injury or risk to your health/yourpatients' health.

Important

Safety note indicating possible damage to the unit/accessory.

Note

Note on important information

2 Warnings and safety notes

Risk of infection

All components of the blood glucose monitor and its accessories may come into contact with human blood and are therefore a possible source of infections.

Warning

- **This blood glucose monitor must display the blood glucose content in mg/dL. The unit of measurement mg/dL accompanies each blood glucose value. Please contact our customer service if the device does not display mg/dL. You risk damaging your health if you measure your blood glucose value using a unit of measurement with which you are not familiar, misinterpret the values and therefore take incorrect measures.**
- When using the blood glucose monitor for various persons, please observe the generally applicable regulations regarding disinfection, safety and contamination.
- Medical carers and others who use this system on several patients must be aware that all products or objects that come into contact with human blood must be handled, even after cleaning, as though they could transfer pathogens.
- The lancing device is suitable for self-testing. Do not share the lancing aid or the lancet needles with others or amongst various patients (**risk of infection!**).
- Use a new, sterile lancet needle for each blood sample (**for single use only**).

General notes

Warning

Do not use the device in the vicinity of strong electromagnetic fields and keep it away from radio systems or mobile telephones.

Measuring the blood glucose content

Warning

- The measurements taken by you are for your information only – they are no substitute for a medical examination! Regularly consult your GP regarding your measured values. Do not alter the procedures prescribed by your GP.
- Despite the simple usage of the Beurer GL44 monitor for self-monitoring of blood glucose levels, you may possibly need to obtain instructions for using the system from your healthcare professional (for example, your GP, chemist or diabetes consultant). Only proper use will guarantee exact measurements.
- A lack of water, high fluid loss, for example perspiration, frequent passing of water, severe hypotension (low blood pressure), shock or hyperosmolar hyperglycaemic non-ketotic coma may lead to incorrect measured results.
- An excessively high or low hematocrit value (proportion of red blood cells) may lead to incorrect measurements. In the event of a very high hematocrit value (above 55%), the displayed blood glucose value may be too low; in the event of a very low hematocrit value (below 30%), it may be too high. Please consult your GP if you do not know your hematocrit value.

- Do not use the test strips to measure blood glucose values on newborns.
- Do not use NaF or potassium oxalate anticoagulants to prepare for venous blood samples.
- Do not test any severely ill patients using this device.
- Lipemia effects: High blood triglyceride values of up to 1000 mg/dL hardly influence the results. However, triglyceride values above this level may affect the blood glucose test.
- High blood cholesterol values of up to 500 mg/dL hardly influence the results. However, cholesterol values above this level may affect the blood glucose test.
- Use fresh capillary whole blood only. Do not use serum or plasma.
- Use capillary blood without squeezing the penetration area. If the area is squeezed, the blood is diluted with tissue fluid and this may lead to an incorrect measuring result.
- Do not use the test strips above an altitude of 7010 m.
- Very high levels of humidity may influence the test results. Relative humidity of more than 90% may lead to inexact results.

Note

- The Beurer GL44 mg/dL measuring system is intended to measure capillary whole blood.

Storage and maintenance

Warning

- Store the blood glucose monitor and its accessories out of the reach of small children and pets. Small parts, such as lancet needles, parts of the lancing device, batteries or test strips may be life-threatening when swallowed. If swallowed, immediately seek medical attention.
- The test strip box contains desiccant, which may irritate the skin or eyes when inhaled or swallowed. Keep the box out of the reach of children.

The blood glucose monitor is made from precision and electronic components. The accuracy of the measurements and service life of the device depend on its careful handling:

- Protect the device and its accessories from impacts, humidity, dirt, strong temperature fluctuations and direct sunlight. Do not store the device, test strips and control solution in your vehicle, in the bathroom or in a cooling appliance!
- Do not drop the device.

Batteries/Saving measured values

Warning

- Keep batteries out of the reach of children. Children may put batteries in their mouth and swallow them. This may severely damage their health. If affected, immediately seek medical attention!
- Normal batteries must not be charged, heated or thrown into an open fire (**risk of explosion!**).

Important

- Do not disassemble or short-circuit the batteries.
- Always replace all batteries at the same time and use batteries of the same type.
- Leaking batteries may damage the device. If you do not intend to use the device for longer periods, remove the batteries from the battery compartment.

Attention!

- Leaked or damaged batteries may burn the skin. In this case, use suitable protective gloves.

Note

- The stored blood glucose values are retained when the batteries are replaced. If applicable, the date and time must be reset after replacing the batteries.
- Use lithium-ion batteries only.

Repairs

Note

- Do not open the device. Failure to comply will result in voiding of the warranty.
- Do not repair the device. Faultless functionality can no longer be guaranteed in this case.
- Do not dismantle the lancing device into individual parts, except in the steps described in these instructions.
- Please contact our customer service for repairs.

Disposal

Warning

- It is essential to comply with the generally applicable safety precautions for handling blood when disposing of materials of the blood glucose monitor. Dispose of all blood samples and materials with which you or your patients come into contact correctly in order to prevent injury and infection of other persons.
- After use, dispose of test strips and lancets in a puncture-proof container.

Note

Batteries must not be disposed of with the household waste. As a consumer, you are required by law to recycle used batteries. You can recycle your old batteries at public collection points in your community or wherever batteries of this type are sold.

The codes below are printed on batteries containing harmful substances:

- Pb = Battery contains lead,
- Cd = Battery contains cadmium,
- Hg = Battery contains mercury.

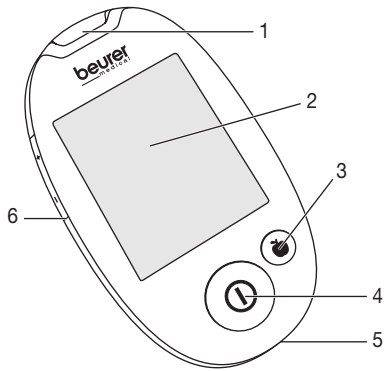
For environmental reasons, do not dispose of the device with the household waste at the end of its service life. Please dispose of the device in accordance with EC Directive 2002/96/EC – WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal.

3 Description of units and accessories

3.1 Blood glucose monitor

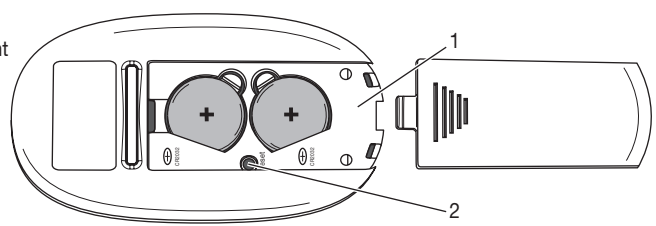
Front

1 Receptacle for test strips, illuminated
2 Display
3 Highlight button
4 On/Off button
5 PC port
6 "+ –" rocker switch



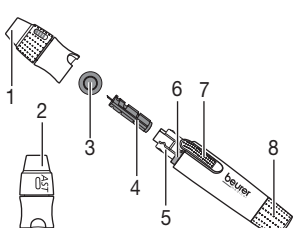
Rear

1 Battery compartment (bottom side)
2 Reset button



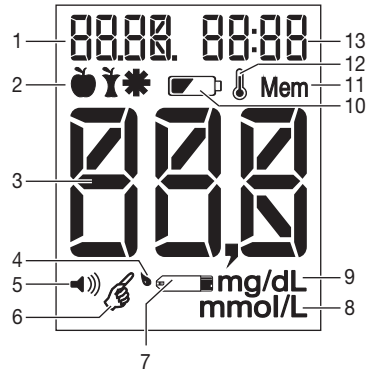
3.2 Lancing aid and lancet needles

1 Cap
2 AST Cap
3 Protective lancet disc
4 Sterile lancet needles
5 Lancet holder
6 Safety switch
7 Trigger
8 Tensioning device



3.3 Display symbols

1 Date
2 Symbols for highlighting measurements
3 Measured value display, HI, LO display, average blood glucose value, Err
4 Blood droplet symbol
5 Speaker symbol
6 Hand symbol
7 Test strip symbol
8 Blood glucose unit mmol/L – not functional
9 Blood glucose unit mg/dL
10 Replace battery symbol
11 Memory symbol
12 Temperature symbol
13 Time

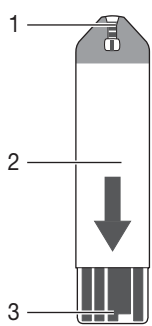


Note

The blood glucose monitor is supplied with the following basic settings:
- Blood glucose unit: mg/dL
- Acoustic signal on
- Backlighting on

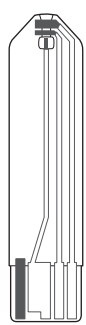
3.4 Test strips

Front



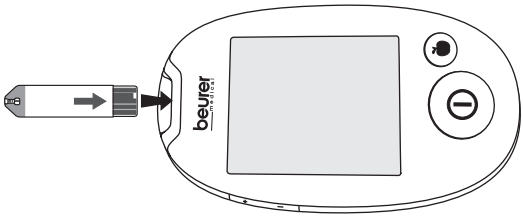
1 Gap for blood input
2 Handle
3 Contacts

Rear



You can identify the rear by the contact tracks.

Insert the test strip into the device so that the contacts are pointing inside the slot.
Please ensure that the front of the test strip is facing you.



Note

Carefully read the following information on handling and storing your test strips. Please observe all notes to ensure that the test strips supply accurate measured results.

Warning

Use each test strip only **once** and for **one** patient only!

Handling test strips

Note

- Immediately securely close the test strip box after taking out a test strip.
- Do not use the test strips if they have expired. The use of expired test strips may lead to incorrect measurements. The expiry date is printed on the box next to the hourglass symbol.
- Test strips expire three months after the box is opened. Make a note of the expiry date (opening date + 3 months) on the label. The shelf life is limited to the expiry date (see date next to the hourglass symbol).
- Do not use the test strips if one of the expiry dates has passed (/).
- You can touch the test strip at any point with clean, dry hands.
- Use the test strip for measurement immediately after removing it from the box.
- Do not bend, cut or otherwise modify the test strips.
- Do not use test strips that have come into contact with fluids.

Storing test strips

Note

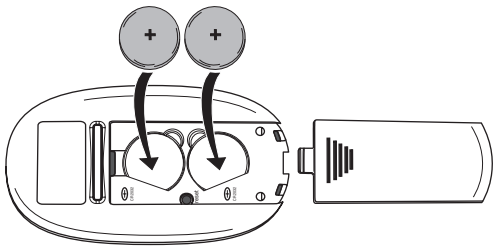
- Keep the test strips in a cool, dry place above +2 °C and below +30 °C. Do not expose the test strips to direct sunlight or heat. Do not store in your vehicle, in the bathroom or in a cooling appliance.
- Permitted relative air humidity below 90 %.
- Keep the test strips in the original box only – never use other containers.

4 Initial use and basic settings

4.1 Removing the battery insulation strips, replacing the batteries

Note

- Two batteries are included in the delivery scope of the blood glucose monitor. These have already been inserted into the battery compartment.
- Remove the insulation strip before initial use.



1. Remove the battery compartment lid on the bottom side of the device.
2. Remove all batteries when replacing batteries. The device retains the date and time as long as one battery is still inserted. If applicable, reset the date and time (see “Making and changing basic settings” on page 14).
3. Insert two new **CR 2032 3 V** batteries. Make sure that the batteries are inserted with the correct polarity, according to the label. Please observe the graphic in the battery compartment.
4. Subsequently close the battery compartment lid carefully.

Note

- The batteries are almost empty if the replace battery symbol appears. Replace both batteries as soon as possible.
- If “LP” appears on the display, the battery power level is so low that no more measurements are possible.

4.2 Making and changing basic settings

1. Remove the batteries and reinsert them. Alternatively, press the “+” button and the On/Off button for a minimum of five seconds.
   An acoustic signal sounds.
   The year display flashes.

2 Setting the date and time

Note

- You must set the date and time. Otherwise, you will not be able to save your measured values correctly with a date and time to retrieve them later.
- The time is displayed in the 24-hour format.

Set the year (calendar to 2099) by pressing the "+" or "–" button. Confirm by pressing the On/Off button [4].
The day display flashes.
Proceed as described above for the month, day, hour and minute.
"dISP LIt" and "on" will be displayed. The background of the display is simultaneously illuminated for a few seconds.

3 Switch backlighting on/off

To switch the blue backlighting off, press the "+" or "–" button.
"dISP LIt" and "OFF" will be displayed. Confirm by pressing the On/Off button [4].
"bEEP", "on" and the speaker symbol are displayed.

4 Switching the acoustic signal on/off

To switch the acoustic signal off, press the "+" or "–" button.
"bEEP" and "OFF" is displayed.
The speaker symbol is no longer shown in the display.
Confirm by pressing the On/Off button [4].
"Mem" and "OK" are displayed.

5 Deleting stored values

Proceed as follows to delete stored values:

- Press the "+" or "–" button. "Mem" and "dEL" are displayed
- Confirm by pressing the On/Off button [4]. "Mem" and "dEL" flash in the display.
- To irreversibly delete your values, press the On/Off button again to confirm. "Mem", "dEL" and "OK" are displayed.

If you do not wish to delete your values, press the "+" or "–" button. "Mem" and "OK" are displayed again. Confirm by pressing the On/Off button.

6 The blood glucose monitor is now ready for operation

5 Measuring blood glucose values

Warning

- If the protective disc on a lancet needle has already been removed, do not use the lancet needle.
- If you have dropped the lancing aid with an inserted lancet needle, carefully pick it up and dispose of the lancet.

Important

- Use the lancing aid only with lancet needles by the same manufacturer. The use of other lancet needles may impede the functionality of the lancing aid.
- If you are using a third-party lancing aid, please read the respective Instructions for Use.

5.1 Preparing to take a blood sample

1 Choose a part of the body from which to take a blood sample. The lancing aid is intended for taking blood samples from the fingertip or other body parts such as the palm of the hand, forearm or upper arm. We recommend taking blood samples from the fingertip. To make the procedure as painless as possible, do not take samples directly from the centre of the fingertip, but slightly to either side.

Warning

- **In the event of suspected hypoglycaemia: take blood from the fingertip only.**
  Reason: changes to the blood glucose level can be determined quickly in blood samples taken from the fingertip.
- Blood samples from the fingertip and samples taken from another body part (AST) may lead to completely different measured results. It is essential to seek medical advice before taking measurements from other body parts.

2 Prepare the following items: blood glucose monitor, test strip box, lancing aid, sterile lancet needle. You will also need the AST cap for measurements at other body parts.

3 Wash your hands with soap and warm water before taking a blood sample. This not only ensures optimal hygiene but also encourages good blood circulation at the puncture area on the finger. Carefully dry your hands. Also ensure that the puncture area is hygienically clean when taking blood samples from other body parts (AST).

Warning

If you have used alcohol for cleaning, ensure that the area has fully dried prior to measuring.

5.2 Taking a blood sample

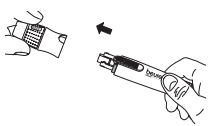
Warning

- Change the puncture area for each measurement, e.g. a different finger or the other hand. Repeatedly using the same area may cause inflammation, numbness or scarring.
- Without the cap, there is a danger of injury from the exposed lancet.
- Do not use the AST cap to take blood samples from the finger.
- Do not squeeze your finger to obtain a larger drop of blood. If squeezed, the blood is diluted with tissue fluid and this may lead to an incorrect measuring result.
- Please note that insufficient blood circulation at the puncture area, e.g. caused by cold temperatures or illness, may lead to incorrect results.

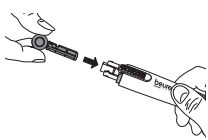
Important

Do not apply any blood samples or control solutions to the test strips before placing these in the measuring device.

1 Remove the cap from the lancing device.

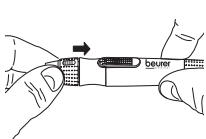


2 Place a sterile lancet needle into the lancing aid and secure the lancet.



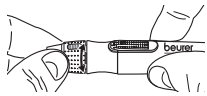
3 Rotate the lancet to remove the protective disc while holding the shaft of the lancet. Keep the protective disc to safely dispose of the used lancet needle after taking a blood sample.

4 Use various caps depending on the area from which you take the sample:
Fingertip: Cap
Other body parts: AST cap (transparent)
Place the selected cap on the lancing device.



5 **Setting the penetration depth**
You can set seven different penetration depths on the lancing device. The penetration depth is displayed by the markings in the cap.
- soft or thin skin
- normal skin
- thick or callous skin

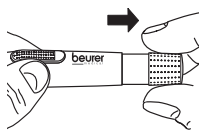
Turn the moving upper part of the cap until the desired penetration depth is displayed.



Note

When using the AST cap, penetration depth does not need to be set.

6 Pull the tensioning device back until it audibly engages. Release the tensioning device. This automatically snaps back into the default position. The lancing device is now ready for use.

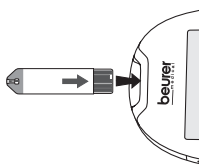


7 Put the already prepared lancing aid to one side and prepare the device for measurement.

8 Take a test strip from the box and immediately close it again.

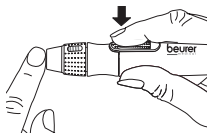
9 Hold the blood glucose monitor so that the display is facing you.

10 Firmly insert a test strip into the device with the contacts first. Please make sure that the front is facing you. You can touch the test strip at any point with clean, dry hands.
Use the test strip within three minutes of taking it from the box.



11 The device automatically switches on and shows the start display. The device is ready for measurement as soon as the hand and the droplet symbol flash.

12 You may now use the lancing aid to take a blood sample. Please ensure that the blood remains a droplet and is not spread. Immediately use the blood droplet to take a measurement.

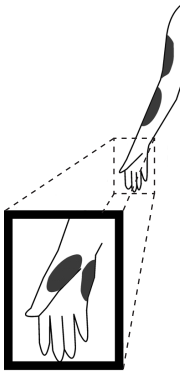


Blood sample from the fingertip

The best penetration areas are the middle finger and the ring finger. Firmly position the lancing aid slightly to the side of the centre of the fingertip. Press the trigger. Remove the lancing aid from the finger. A round drop of blood of at least 0.6 microlitres (corresponds to approx. 1.4 mm, original size: ●) must have formed.

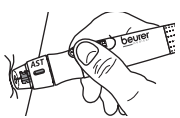
Blood samples from other body parts (AST)

Find a soft area away from bones, without any visible blood vessels and with as little hair as possible. Warm the penetration area to enhance circulation by gently massaging the area. Press and hold the lancing aid against the penetration area for a few seconds and subsequently press the trigger.
Continue to hold the lancing aid against the skin until a round drop of blood has formed under the cap. Maintain the pressure until the drop of blood reaches a size of at least 0.6 microlitres (corresponds to approx. 1.4 mm, original size: ●)
Carefully lift the lancing aid off the skin.



Note

Only take blood from other areas at the following times:
- On an empty stomach (more than two hours after most recent meal).
- At least two hours after administration of insulin.
- At least two hours after physical activity.



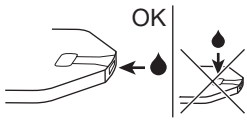
Please also note the following:
- If the blood glucose test results do not match how you feel, carry out another test using blood from the fingertips.
- DO NOT change your treatment purely on the basis of a measurement that was carried out using blood taken from an alternative area. Carry out another test with blood from the fingertips in order to confirm the test result.
- If you often fail to notice that you have a low blood glucose level, carry out a test using blood from the fingertips.

13 If there is an insufficient amount of blood, repeat steps 1 to 12 with a greater penetration depth.

Note

When using the AST cap, repeat measurement at different parts of the body.

14 Hold the blood input gap (at the tip of the test strip) to the drops of blood until the gap is completely filled and the measuring device in the display starts counting backwards. Do not press the penetration area (fingertip or other body parts) to the test strip. The blood must not be spread. The blood is sucked into the gap.



Note

Error message “002” appears on the display if the gap was not correctly and sufficiently filled with blood. Repeat the measurement using a new test strip and a greater penetration depth.

Note

- Do **not** add blood later if the device does not start measurement. Remove the test strip and end this test. Use a new test strip.
- The device switches itself off if the test strip has already been inserted into the device but no blood is added to the test strip within two minutes. Briefly remove the test strip and reinsert it so that the device automatically switches itself back on.
- Contact our customer service if you are unable to fully cover the test strip in blood.
- If you are measuring in a dark environment, press the On/Off button to switch the device on. The test strip light switches on and makes it easier to insert the test strip. The backlight is also switched on in the results display.

5.3 Reading out result and highlighting measurements

Evaluating result

As soon as the gap is sufficiently filled with blood, the device performs the blood glucose measurement. The blood glucose monitor counts down for approx. five seconds.
The measured result is subsequently shown on the display.

Read the measured values. For explanations and measures for the measured values, see chapter “5.5 Evaluating measured blood glucose values”. If an error message is displayed, read chapter “8. What if there are problems?”

Highlighting measured values

You have the following options to highlight measured values.

	Before meals.
	After meals.
	General highlight (e.g. after exercising).

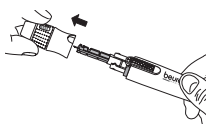
Highlighting measured values enables you, your GP or diabetes consultant to better check your blood glucose values. For example, you can display the average values of all measurements taken before meals.

The measured value can be highlighted as soon as it is displayed. You cannot highlight it later. For this purpose, briefly press the highlight button [3].
a) Pressing once highlights the value with .
b) Pressing again highlights the value with .
c) Pressing yet again highlights the value with .
d) Pressing once more removes the highlight.

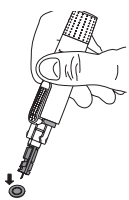
The selected highlight is stored in the memory of the device when it is switched off.

5.4 Post-processing and disposal

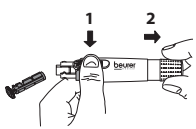
1. Remove the test strip from the device and carefully dispose of it according to the currently applicable regulations to avoid infecting others.
2. Carefully undo the cap from the lancing device and remove it.



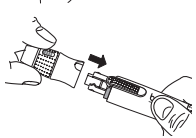
3. Place the stored protective disc flat on a hard surface. Stick the tip of the needle into the protective disc so the needle is covered. Take care not to touch the used lancet.



4. Press and hold the trigger and pull the tensioning device with your other hand. This causes the lancet to drop out of the holder. Carefully dispose of all blood samples and materials that came into contact with you or your patient. Dispose of the lancet in a puncture-proof container. This prevents injuries and the infection of others.



5. Replace the cap onto the lancing device.



5.5 Evaluating measured blood glucose values

Your blood glucose monitor can process values between 20 and 630 mg/dL. The "Lo" warning is displayed for measured results below 20 mg/dL. The "Hi" warning is displayed for measured results above 630 mg/dL.

Warning

- If you suspect that the blood glucose results are incorrect, first repeat the test and, if applicable, perform a functional test using control solution. Seek medical advice if doubtful results persist.
- Immediately seek medical attention if your symptoms are not in line with your measured blood glucose values and you have observed all instructions for the Beurer GL44 blood glucose monitoring system.
- Do not ignore symptoms of too high/low blood glucose levels. Seek medical attention.

Blood glucose

The following table provides a classification of blood glucose values according to the diabetes guidelines of the Deutsche Diabetes Gesellschaft (DDG, German diabetes association).

Time of blood glucose measurement	Normal blood glucose values	Suspicion	Diabetes
With an empty stomach			
• Whole blood, capillary (haemolysed)	Below 90 mg/dL	90–109 mg/dL	≥ 110 mg/dL
• Plasma venous	Below 100 mg/dL	100–125 mg/dL	≥ 126 mg/dL
Two hours after a meal	Below 140 mg/dL	140–199 mg/dL	≥ 200 mg/dL

Source: Deutsche Diabetes Gesellschaft (DDG) 2009

Evaluating critical measured values

Display	Blood glucose	Action
	Very low blood glucose level Below 20 mg/dL	Immediately seek medical attention.
	Low blood glucose level Below 70 mg/dL	Have a suitable snack. Follow your GP's instructions.
	High blood glucose level On an empty stomach above 100 mg/dL Two hours after a meal Above 140 mg/dL	If this high value persists two hours after your last meal, this may indicate hyperglycaemia. Seek medical attention to coordinate any measures, if applicable.
	High blood glucose level, possibly ketones Above 240 mg/dL	Perform a ketone test. For this purpose, seek medical attention.
	Very high blood glucose level Above 630 mg/dL	Take another measurement using a new test strip. If the result is identical: seek medical attention immediately.

5.6 Functional check with control solution

The control solution is used to test the entire blood glucose monitoring system. This helps to determine whether the monitor and the test strips are working optimally together and whether the test was performed correctly.
Perform the control solution test if you suspect that the blood glucose monitor and/or the test strips could be faulty or if you have repeatedly measured unusual blood glucose values. Also test the blood glucose monitor if it has fallen down or is damaged. The control solution is available separately. Please observe the additional notes in the Instructions for Use of the control solution for the test.

Important

- Do not use third-party control solution. Correct functioning of your measuring device can only be tested using Beurer control solutions (LEVEL3 + LEVEL4).
- Control solution measurements: When using the device, specialist personnel must follow statutory guidelines.
- Do not apply any blood samples or control solutions to the test strips before placing these in the measuring device.

Performing a functional test using control solution

Warning

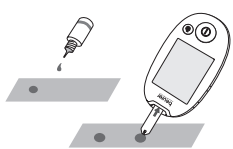
To obtain correct results, the measuring device, the test strip and the control solution must be the same temperature. For the “Functional test using the control solution”, the temperature is to be between 20 °C and 26 °C.

1. Hold the blood glucose monitor so that the display is facing you.
2. Insert a test strip into the slot on the blood glucose monitor with the contacts first. Make sure that the front of the test strip is facing you (see “Test strip” on page 12).
3. The device automatically switches on and briefly shows the start display. The device is ready for measurement as soon as the hand and the symbol flash.

   IMPORTANT: Control solutions and blood react to temperature influences in different ways. It is therefore of vital importance that control solution measurement is always performed in control solution mode. If this mode is not used, results may be obtained that are outside the target range.

   Note

   Press the rocker switch “+” or “–” to change to the control mode. “CtL” is shown on the display. This means that the result value is not stored in the memory, therefore not influencing your measured value statistics. Press “+” or “–” again. “CtL” disappears from the display and the value is stored normally in the memory.
4. A clean surface is required to perform a correct functional test.
   Shake the control solution well before use.
   Undo the cap and press two drops next to each other on the clean surface without touching them. Use the second drop for the measurement.



   Note

   Do not apply the drop directly to the test strip to avoid contaminating the remaining control solution in the bottle by touching the test strip with the tip of the bottle.
5. Hold the input gap (at the tip of the test strip) to the drops of control solution until the gap is completely filled and the measuring device in the display starts counting backwards.
   If the gap is sufficiently filled with solution, the device performs a measurement. The devices counts down for approx. five seconds. The measured result is subsequently shown on the display.
6. Check whether the result is within the specified range of results for the control solution. This range of results is printed on the test strip box.

Expected results

At room temperature, the measured values of the test using the control solution should be within the range printed on the test strip box in approx. 95 % of all tests.

Warning

The result range printed on the test strip box applies only to the control solution. **This is not a recommended value for your blood glucose level.**

If measured values are outside the specified range, check the following possible causes:

Cause	Action
• The first drop of control solution was not disposed of. • The tip of the bottle was not cleaned correctly. • The bottle was not shaken well enough.	Rectify the cause and repeat the test.
Control solution and/or test strips have passed their expiry date or are contaminated.	Repeat the test using a new bottle of control solution and/or new test strip.
The control solution, test strips or blood glucose monitor are too warm or too cold.	Bring the control solution, test strips and blood glucose monitor to room temperature (+20 °C to +26 °C) and repeat the test.
The test strips and control solution were kept at temperatures and in humidity outside the specified range.	Repeat the test using new/correctly stored test strips and control solution.
Damaged test strips. For example • Test strips that were exposed to fresh air for too long. • The test strip box was not closed completely.	Repeat the test using a new test strip and/or a new box of correctly stored test strips.
Old test strips.	Open a new box of test strips. Repeat the test.
There is a problem with the blood glucose monitor.	Contact our customer service.
Functional test was incorrectly performed.	Repeat the test and follow the instructions.

Warning

Do not use the system to measure your blood glucose level if you are repeatedly provided with measured values outside the specified range when using control solution. Contact our customer service.

6 Measurement memory

For each measurement, your blood glucose value is automatically saved with the date and time unless "CtL" was activated for a blood glucose measurement using control solution.
The memory can store a maximum of 480 measured values. If the memory is full, the oldest value is replaced by the most recent value. You can call up every individual measured blood glucose value. You can also calculate and display the average value for the last 7, 14, 30 and 90 days.

Note

- If you have already saved measured values and you reset the date, the average values are calculated as from the new period.
- "---" indicates an empty memory for measured values. Press the On/Off button to switch off the device.

6.1 Displaying individual values

Individual values of the last 480 measurements are displayed. The most recent measured value is displayed first, and the oldest last. The blood glucose monitor simultaneously shows the date and time.

1. Switch the monitor on using the on/off button [4]. The initial display is shown briefly. Press the "+" or "–" rocker switch [6].
2. "Mem" and the number of saved blood glucose tests are displayed briefly (Image 1). The display then changes to the saved values including the measurement unit, date, time, "Mem" and any possible highlighting. (Image 2).

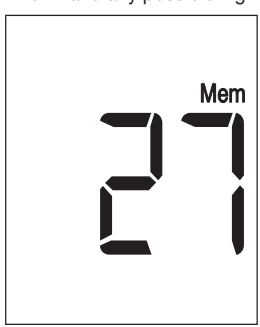


Image 1

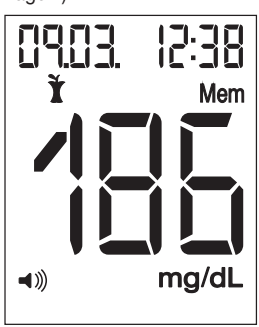


Image 2

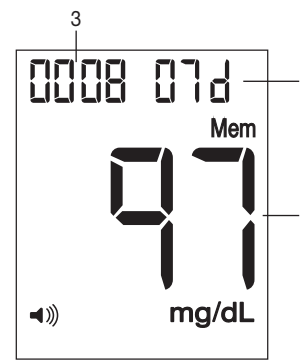
3. Pressing the rocker switch "–" [6] will each time display the memory space number and then the previous measured value. You can display a maximum of 480 previous measurements.
4. You can cancel the process at any time. For this purpose, press the On/Off button or wait until the device switches itself off automatically after two minutes.

6.2 Displaying average blood glucose values

You can display the average measured blood glucose value from the last 7, 14, 30 and 90 days.

1. Switch the monitor on using the on/off button [4]. The initial display is shown briefly. Press the "+" rocker switch twice [6].
   The measurement unit of the blood glucose value, "07 d" and the average value are displayed.
2. Press "+" [6] repeatedly to display the average value for 7, 14, 30 and 90 days.
3. You can cancel the process at any time. For this purpose, press the On/Off button or wait until the device switches itself off automatically after two minutes.

Pos.	Explanation
1	Average value
2	Time period, e.g. 7
3	Number of saved values used to calculate the average



6.3 Displaying average blood glucose values for highlighted values

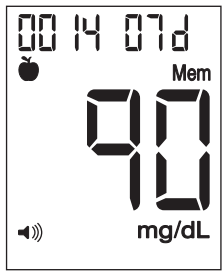
You can display the average measured blood glucose value for highlighted values from the last 7, 14, 30 and 90 days.

1. Switch the monitor on using the on/off button [4]. The initial display is shown briefly. Press the "+" rocker switch twice [6].
   The measurement unit of the blood glucose value "07 d" and the average value of all measurements are displayed.

2 Press “+” [6] repeatedly to display the average value of all measured values for 14, 30 and 90 days.

After the display of the 90-day average value of all measured values
- the seven-day average for values measured “before meals”,
- the symbol,
- the unit of measurement for blood glucose values and
- “07d”

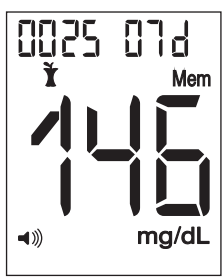
are shown on the display.



Press “+” [6] repeatedly to display the average blood glucose level from the last 14, 30 and 90 days “before meals” .

After displaying the average value for 90 days “before meals”
- the seven-day average for values measured “after meals”,
- the symbol,
- the unit of measurement for blood glucose values and
- “07d”

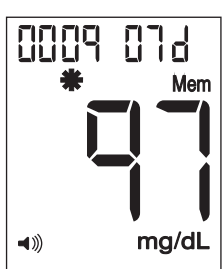
are shown on the display.



Press “+” [6] repeatedly to display the average blood glucose level from the last 14, 30 and 90 days “after meals” .

2 After displaying the average value for 90 days “after meals”
- the average for the last seven days of values highlighted as “general”,
- the symbol,
- the unit of measurement for blood glucose values and
- “07d”

are shown on the display.

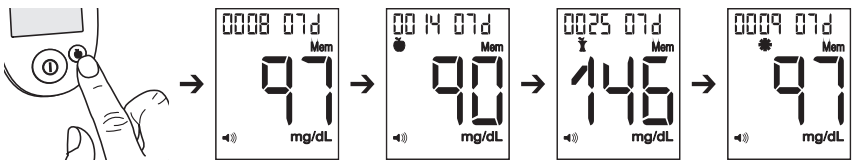


Press “+” [6] repeatedly to display the average blood glucose level from the last 14, 30 and 90 days for values highlighted as “general” ✱.

3 You can cancel the process at any time. For this purpose, press the On/Off button or wait until the device switches itself off automatically after two minutes.

Tip: Speed function

You are in the measurements memory. By pressing the highlight button [3], you can switch to the different 7-day average values. In this way, you can get to the desired average value more quickly. For example:



6.4 Deleting individual measured values from the memory

1 Press the buttons as described in 6.1 until the value appears that you would like to delete.

2 Press and hold the On/Off button. Additionally press the “–” button for two seconds.
“dEL”, “Mem” and the number of the value to be deleted flash.
Press the On/Off button again. “dEL”, the number of the value to be deleted, “Mem” and “OK” are displayed.
If you do not wish to delete the value, briefly press the “+” or “–” button. You are taken back to the memory spaces.

3 The device subsequently displays that the following measured value has moved to the memory space of the deleted measured value.

6.5 Deleting the entire memory for measured values

You have two options to delete the measured value memory.
Option 1: Proceed as described in “4.2 Making and changing basic settings”.
After explaining how to set the beep, the section explains how to delete the measured value memory.
Option 2 is described in the following chapter.

6.6 Reset to basic settings

1 The blood glucose monitor must be switched off.

2 Remove the battery compartment lid.

3 Press the ‘RESET’ button for 1 second. All settings and measured values are subsequently deleted.

4 Close the battery compartment lid again.

5 The blood glucose monitor is now in the settings mode.

6.7 Transferring measurements to a PC

The GL44 blood glucose monitor includes a PC interface [5] that enables you to transfer measured values saved on the device to a PC (for the position of the port, see page 11). Beurer blood glucose software is available as a free download at www.beurer.com. This software enables you to evaluate your measured values, add insulin doses and print results. The software helps you and your GP to better monitor your blood glucose level.
For more information, please read the instructions for use of the blood glucose diary software (also available to download). There you will find all the information required for the data transfer and a detailed description of the software.

The GL44 monitor is also compatible with Diabass and SiDiary.

Note

- An effective evaluation is only possible if you have correctly set the date and time (see page 14).
- During data transfer, no measurements can be taken.
- The measurements remain saved on the blood glucose monitor after they have been transferred to the PC.

Important

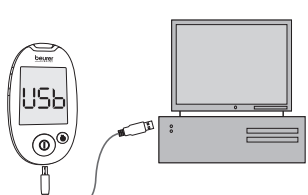
Use only the USB cable provided for data transfer. Otherwise you may damage your blood glucose monitor or PC.

Preparation

- Position the blood glucose monitor near to your PC.
- Connect the GL44 monitor to your PC using the USB cable provided.
- Install the blood glucose diary software on your PC as described in the instructions for use of the software.

Transferring measurements

1 The blood glucose monitor must be switched off. Insert the larger, flat USB connector of the connection cable into a USB port on your PC. Insert the mini USB connector into the integrated PC interface socket on the GL44 monitor.



2 "USb" is shown on the display of the blood glucose monitor. The blood glucose monitor is now ready for the data transfer.

3 Follow the information on data transfer and evaluation provided in the software and the instructions for use of the software.

7 Storing, maintaining and disinfecting the device

Storing

Keep the Beurer GL44 blood glucose monitor in the case supplied after each measurement and do not expose it to direct sunlight.

Note

- Do not store the device, test strips and control solution in your vehicle, in the bathroom or in a cooling appliance!
- Retain these Instructions for Use.
- Remove the batteries if you do not intend to use the device for a prolonged period of time.

7.1 Cleaning

Device

Only clean the device when it is switched off.
Clean the surface of the device using a soft, slightly damp cloth (water or a mild cleaning solution). Dry the device using a lint-free cloth.
Make sure that moisture does not enter the test strip insertion slot. Do not spray cleaning agent directly on the device. Do not submerge the device in water or any other fluids and make sure that no fluids can enter the device.

Lancing device

Clean the surface of the lancing device using a soft, slightly damp cloth (water, a mild cleaning solution or rubbing alcohol). The lancing device must not be immersed in water or other liquids or be cleaned in the dishwasher. Dry the lancing aid using a lint-free cloth.

7.2 Disinfection

Device

Please comply with the generally applicable guidelines on disinfection when using the device on different persons. Do not submerge the device in disinfection solutions or any other fluids and make sure that no fluids can enter the device.

Note

The blood glucose monitor is made of precision components. The accuracy of the measurements and service life of the device depend on its careful handling:

- Protect the device from impacts and do not drop it.
- Protect the device from damaging factors such as moisture, dirt, dust, blood, control solution or water, strong temperature fluctuations, direct sunlight and extreme cold.
- Do not use the device in the vicinity of strong electromagnetic fields, radio systems or mobile telephones.

8 What if there are problems?

Display messages on batteries and blood glucose measurement

No.	Cause	Solution
LP	Batteries empty.	Replace all batteries.
Ht	Temperature of the measuring environment, blood glucose monitor or test strip above the permitted range.	Repeat the test using a new test strip as soon as the measuring environment, blood glucose monitor and test strips have reached room temperature (+20 °C to +26 °C).
Lt	Temperature of the measuring environment, blood glucose monitor or test strip below the permitted range.	Repeat the test using a new test strip as soon as the measuring environment, blood glucose monitor and test strips have reached room temperature (+20 °C to +26 °C).
Err	Used or contaminated test strip inserted.	• Insert unused test strip that has not expired. • Repeat the blood glucose measurement.
Err001	System error.	Remove batteries, reinsert batteries. Contact our customer service if the problem persists.
Err002	Insufficient amount of blood on the test strip.	Repeat the measurement using a new test strip.
Err005	System error.	Remove batteries, reinsert batteries. Contact our customer service if the problem persists.
	Unknown error messages.	Remove batteries, reinsert batteries. Contact our customer service if the problem persists.

Problem: device does not switch on

Cause	Solution
Batteries empty.	Replace batteries.
Incorrectly inserted or missing batteries.	Check whether the batteries have been inserted correctly (see “Inserting and replacing the batteries” page 14).
Test strip inserted incorrectly or not completely.	Firmly insert the test strip into the slot on the device with the contacts first. Make sure that the front of the test strip is facing you (see “Test strip” on page 12).
Device faulty.	Contact customer service.

Problem: the test does not start after inserting the test strip into the device and applying blood

Cause	Solution
Insufficient amount of blood or test strip not filled correctly.	Repeat test using a new test strip and a larger drop of blood. Please note the correct filling of the test strip (see page 20).
Faulty test strip.	Repeat the test using a new test strip.
Blood was applied while the device was switched off.	Repeat the test using a new test strip and only apply blood after and flash.
The basic settings of the device were changed and the changes were not completed (see "Making and changing basic settings" on page 14).	Remove the test strip and press the "On/Off" button until "OFF" is displayed. Repeat test.
Device faulty.	Contact customer service.

9 Technical specifications

Dimensions (W x H x D)	52 x 95 x 16 mm
Weight	44 g incl. batteries
Power supply	2 x 3 V CR 2032 button cell batteries
Battery life	More than 1000 measurements
Measured value memory	480 measured values with date/time Data retained upon changing batteries
Average values	for 7, 14, 30, 90 days
Automatic switch-off	Two minutes after last actuation
Storage/ transport temperature	Temperature: +2 °C – +30 °C Relative humidity: < 90 %
Operating ranges	Temperature: +10 °C – +40 °C Relative humidity: < 90 % non-condensing
Measuring range, glucose	Glucose: 20–630 mg/dL
Blood sample	capillary whole blood
Amount of blood	0.6 microlitres
Blood glucose measuring duration	Approx. 5 seconds
Calibration	Plasma
Test procedure	Amperometric bio sensor
Using the device	Suitable for self-testing
System function test	Upon every switch-on

EMC

This device complies with the European standard EN 61326 and is subject to particular precautions with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit. For more details, please contact our customer service at the address indicated.

Test strip functionality

Test strips enable a quantitative measurement of the glucose level in fresh whole blood. When the gap for taking blood comes into contact with a drop of blood, it is automatically filled by simple capillary action. The blood is sucked into the absorbing gap on the test strip and the blood glucose monitor measures the blood glucose level in the blood.
The test is based on the measurement of an electric current that is generated by the chemical reaction of the glucose with the enzyme glucose dehydrogenase (Aspergillus sp.) on the strip.
During the reaction, a mediator transports electrons through the electrode surface and so generates a current.
The blood glucose monitor analyses this current. The current flow is proportional to the glucose content in the blood sample. The results are shown on the blood glucose monitor display. Only a small amount of blood is required (0.6 microlitres) and measurement duration is approx. five seconds. The test strip detects blood glucose values from 20 to 630 mg/dL.

Chemical components of the test strip sensor

- FAD glucose dehydrogenase 6 %
- Potassium ferricyanide 56 %
- Non-reactive components 38 %

Control solution functionality

The control solution contains a fixed amount of glucose that reacts with the test strip. A test with control solution is similar to a blood test. However, control solution is used instead of blood. The measured result using control solution must be within the result range. This range is printed on each test strip box.

Chemical composition of the control solution

The control solution is a red solution with the following D-glucose level (in percentage shares):

Ingredients	Control solution LEVEL 3	Control solution LEVEL 4
D-glucose	0.14 %	0.37 %
Non-reactive components	99.86 %	99.63 %

Standards

The Beurer GL44 monitor corresponds to European guidelines IVD (98/79/EC) and MDD (93/42/EC).

Comparison of measured values with laboratory values

Performance characteristics: accuracy and precision
Whole blood glucose test results were compared to the YSI 2300 laboratory device. At a concentration of < 75 mg/dL, ≥ 98 % were at +/-15 mg/dL, while at a glucose concentration of ≥ 75 mg/dL, ≥ 98 % were within 20 % of the reference values. The CV (coefficient of variation) is < 5 %. The blood glucose monitor is therefore comparable to a laboratory system.

You will find further details and information regarding blood glucose results and various technologies in generally relevant specialist medical literature.

Usage limits for specialist personnel from the healthcare sector:

1. If the patient shows the following symptoms, it may be the case that no correct values can be displayed:
   - Acute dehydration
   - Acute hypotension (low blood pressure)
   - Shock
   - Hyperosmolar hyperglycaemic condition (with or without ketosis)
2. Lipaemic samples: cholesterol levels up to 500 mg/dL and triglycerid levels up to 1000 mg/dL do not influence the results. Severely lipaemic blood samples were not tested with the Beurer GL44 blood glucose monitor; therefore, using the device with these samples is not recommended.
3. In the case of severely ill patients, blood glucose monitors for home use should not be used.
4. The influence of interfering substances on the measurements depends on the concentration in the blood. The maximum concentrations of certain substances listed below do not significantly influence the measurements.

Influence / Blood glucose value / Concentration of tested substances		80 mg/dL	120 mg/dL	500 mg/dL
Ascorbic acid,	4 mg/dL	10.9%	-1.8%	4.6%
Ibuprofen,	50 mg/dL	3.1%	2.9%	4.6%
L-dopa,	1.8 mg/dL	10.6%	7.9%	4.9%
Sodium Salicylate,	50 mg/dL	-2.6%	9.4%	-0.8%
Tetracycline,	1.5 mg/dL	-5.3%	3.8%	3.2%
Tolbutamide,	100 mg/dL	-2.6%	12.3%	0.9%
Bilirubin-unconjugated,	2.4 mg/dL	-2.5%	4.1%	-0.2%
Uric acid,	8 mg/dL	2.7%	9.6%	-1.8%
Xylose,	4 mg/dL	7.6%	0.8%	7.5%

10 Guarantee and customer service

Warranty

We offer a 3-year product warranty against material and production faults.
The warranty does not cover:

- Damage due to improper operation
- Wearing parts
- Deficiencies already known to the customer upon purchase
- Cases of personal negligence on the part of the customer
- Outside interference

The warranty does not affect the customer's statutory rights. To assert a warranty claim within the warranty period, the customer must provide proof of purchase. The warranty claim must be submitted within a period of 3 years from the date of purchase to BEURER GmbH, Söflinger Straße 218, D-89077 Ulm (Germany). In the event of a warranty claim, the customer reserves the right to have the goods repaired at our own workshop or at a workshop authorised by us. No further rights are granted to the customer (on the basis of the warranty).

Customer service address

Please contact our customer service if you have any questions: Please refer to the address list enclosed for our customer service address.

OUR COMMITMENT TO YOU: We aim to satisfy you by providing high-quality medical products and the best customer service. Please contact our customer service if you are not entirely satisfied with the product.

beurer
medical

GL44_mg/dL_0913_GB Subject to errors and changes